

REMARKS

Status of Application

Claims 31 and 34 stand rejected under 35 U.S.C. § 102(g). Claim 33 is said to be rejected on the cover sheet of the Office Action. However, the text of the Office Action rejects only claims 31 and 34. Claims 1-30 and 32 were previously cancelled.

History of this Application

This application has been pending since May 1995. All of the pending claims – claims 31, 33 and 34 – were found allowable in May 1997. However, prosecution was then suspended due to a potential interference. See May 8, 1997 Office Action (Exhibit A).

The present 102(g) rejection was first made against the pending claims almost five years ago. See November 7, 2003 Office Action (Exhibit B). Applicant presented the 102(g) rejection to the Board of Patent Appeals and Interferences almost three ago. See June 24, 2005 Appeal Brief (Exhibit C). Prosecution was reopened, due to a now-withdrawn interference estoppel rejection, only to return to the same place as it was in November 2003: the 102(g) rejection. It is well past the time that this rejection should be resolved in applicant's favor. It finds no support in the law or on the facts.

The Rejection: 35 U.S.C. § 102(g)- Anticipation

Claims 31 and 34 stand rejected under 35 U.S.C. § 102(g) as being anticipated by either one of Sugano et al., U.S. Patent 5,514,567 (“the Sugano ‘567 patent”) or Sugano et al., U.S. Patent 5,326,859 (“the Sugano ‘859 patent”). The Examiner states that each of the Sugano patents recites a DNA that encodes the same amino acid sequence as is recited in claim 34. The

Examiner also states that each of the Sugano patents recites a DNA that is embraced by claim 31, parts 1 (a) and (b). Finally, the Examiner states that each of the Sugano patents recite methods of using IFN- β in the treatment of human cancers and viral diseases that are embraced by claims 31 and 34. Applicant traverses.

Neither Sugano patent is 35 U.S.C. § 102(g) art to pending claims 31 or 34. As a matter of law, the Sugano patents cannot form the basis of a 102(g) rejection.

35 U.S.C. § 102(g) recites in pertinent part:

“A person shall be entitled to a patent unless –

(g)(2) before such person’s invention thereof, *the invention was made in this country by another inventor* who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other” (emphasis added).

The Sugano patents are not evidence of an invention made in this country. Nor are they evidence of an actual reduction to practice of applicant's claimed invention in this country. See, MPEP § 2138.

“To qualify as prior art under 35 U.S.C. 102(g), . . . *there must be evidence that the subject matter was actually reduced to practice*, in that conception alone is not sufficient. See *Kimberly-Clark*, 745 F.2d at 1445, 223 USPQ at 607. While filing of an application for patent is a constructive reduction to practice, the filing of an application does not itself provide evidence necessary to show an actual reduction to practice of any of the subject matter disclosed in the application as is necessary to provide the basis for an ex parte rejection under 35 U.S.C. 102(g)” (emphasis added).

See also, *In re Clemens*, 622 F.2d 1029, 1038-39; 206 USPQ 289, 298-99 (CCPA 1980) (even a United States patent based on an earlier-filed patent application is not 102(g) art). Thus, under all of 102(g), MPEP § 2138 and *Clemens*, United States patents/applications can never be evidence of an actual reduction to practice or a making of the invention in this country under 102

(g). And, even if they were (which they are not), Sugano's patents are too late. Applicant is entitled to earlier dates than the earliest US filing dates of the Sugano patents. See discussion, *infra*. For all of these reasons, the 102(g) rejection should be withdrawn.

The Examiner does not deny that 102(g) requires that the claimed invention be made in the United States before the effective date of applicant's claims. Rather, the Examiner contends that the Sugano patents disclose the same amount of information relevant to the methods claimed in the pending application. Whether or not that is true, it is irrelevant. Applicant has priority dates earlier than any United States filing date to which the Sugano patents may be entitled. The earliest United States application that led to the Sugano patents was filed on October 27, 1980. Applicant's claims are entitled to at least the June 6, 1980 filing date of his UK patent application 80.18701. The Examiner has never denied that applicant is entitled to such benefit. Indeed, earlier in the prosecution of this application, the Examiner withdrew a 102(e) rejection of substantially the same claims, that now stand rejected, over the very same Sugano patents, because applicant had priority dates earlier than Sugano's earliest U.S. filing date. The same fate should befall the present 102(g) rejection. It should be withdrawn as contrary to the law.

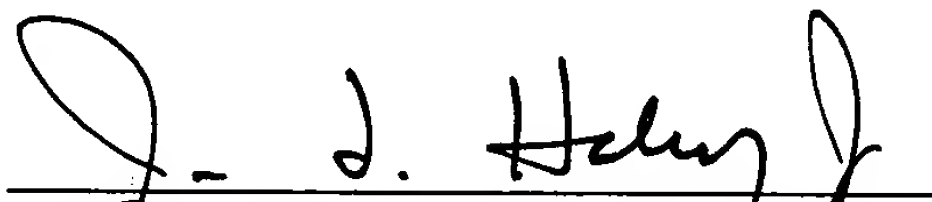
The Examiner also points to the Federal Circuit's decision in *Fiers v. Sugano* and argues that there Sugano was awarded priority to a patentably indistinct invention. That priority award was, however, based solely on Sugano's Japanese filing dates—at best a constructive reduction to practice in Japan. Such Japanese priority dates cannot be considered in a 102(g) rejection. As demonstrated above, a 102(g) rejection requires an actual reduction to practice in the United States before applicant's priority date. The Sugano patents do not evidence such early actual reduction to practice and neither does the Federal Circuit's decision.

For both reasons, then the pending 102(g) rejection must fail. It is not supported in the law or by the facts. Reconsideration and allowance of the pending claims are requested.

Conclusion

For all of the reasons set forth herein, applicant respectfully requests that all of the pending claims be allowed.

Respectfully submitted,



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1. The first part of the exhibit is a photograph of a building, which appears to be a school or a public institution. The building is a two-story structure with a prominent central entrance and several windows. The photograph is in black and white and is somewhat faded.

2. The second part of the exhibit is a document, which appears to be a letter or a report. The text is handwritten and is difficult to read. It seems to be a personal communication, possibly a letter from a family member or a friend.

3. The third part of the exhibit is a photograph of a person, who appears to be a woman. She is wearing a dark coat and is standing in front of a building. The photograph is in black and white and is somewhat faded.

4. The fourth part of the exhibit is a document, which appears to be a letter or a report. The text is handwritten and is difficult to read. It seems to be a personal communication, possibly a letter from a family member or a friend.

5. The fifth part of the exhibit is a photograph of a person, who appears to be a woman. She is wearing a dark coat and is standing in front of a building. The photograph is in black and white and is somewhat faded.

6. The sixth part of the exhibit is a document, which appears to be a letter or a report. The text is handwritten and is difficult to read. It seems to be a personal communication, possibly a letter from a family member or a friend.

7. The seventh part of the exhibit is a photograph of a person, who appears to be a woman. She is wearing a dark coat and is standing in front of a building. The photograph is in black and white and is somewhat faded.

8. The eighth part of the exhibit is a document, which appears to be a letter or a report. The text is handwritten and is difficult to read. It seems to be a personal communication, possibly a letter from a family member or a friend.

9. The ninth part of the exhibit is a photograph of a person, who appears to be a woman. She is wearing a dark coat and is standing in front of a building. The photograph is in black and white and is somewhat faded.

10. The tenth part of the exhibit is a document, which appears to be a letter or a report. The text is handwritten and is difficult to read. It seems to be a personal communication, possibly a letter from a family member or a friend.



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, DC 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/452,658	05/25/95	FIERS	88/88-CIF-D1

JAMES F HALEY JR
FISH AND NEAVE
1251 AVENUE OF THE AMERICAS
NEW YORK NY 10020-1104

18M2/0508

RECEIVED

MAY 13 1997

EXAMINER
MARTINELLI, J

ART UNIT
1804

PAPER NUMBER
//

FISH & NEAVE - PATENT DEPT.
REFERRED TO BAR
BY BRK

DATE MAILED: 05/08/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

See the attached.

Serial No. 08/452,658

Art Unit 1804

All claims are allowable. However, due to a potential interference, ex parte prosecution is SUSPENDED FOR A PERIOD OF SIX MONTHS from the date of this letter. Upon expiration of the period of suspension, applicant should make an inquiry as to the status of the application.

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Art Unit 1804 at (703) 305-3014. The faxing of such papers must conform with the rules published in the Official Gazette, 1156 OG 61 (November 16, 1993).

Any inquiry concerning this communication should be directed to J. Martinell at telephone number (703) 308-0296.


JAMES MARTINELL, PH.D.
SENIOR LEVEL EXAMINER
GROUP 1800

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UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/452,658	05/25/1995	WALTER C. FIER	B8/B8-CIP-DIV 4	5499

7590 11/07/2003
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NOV 11 2003

FISH & NEAVE - PATENT DEPT.
REFERRED TO BT
NOTED BY BT

EXAMINER
MARTINELL, JAMES

ART UNIT.	PAPER NUMBER
1631	

DATE MAILED: 11/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**REMINDER - PLEASE INITIAL
THIS DOCUMENT TO INDICATE
THAT YOU HAVE SEEN IT**

DOCKETED FOR Feb. 7, 2004

Office Action Summary

Application No.

08/452,658

Applicant(s)

FIERS, WALTER C.

Examiner

James Martinell

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31,33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31,33 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 7/14/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 31, 33, and 34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 37 of copending Application No. 08/253,843 and claims 31, 33, and 34 of copending Application No. 08/449,930. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method claims overlap in scope since the polypeptide to be administered is the same. Applicant's offer to submit a proper Terminal Disclaimer or to cancel conflicting subject matter is acknowledged.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Claims 31 and 34 are rejected under 35 U.S.C. 102(g) as being clearly anticipated by either one of Sugano et al (U.S. Patent No. 5,514,5657) or Sugano et al (U.S. Patent No. 5,326,859). Each of the Sugano et al patents discloses a DNA that encodes the same amino acid sequence as is recited in claim 34 (*e.g.*, see Table 5 in each of the references). Additionally the DNA in Table 5 of each of the Sugano et

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al references would hybridize to the DNAs mentioned in claim 31 of the instant application (*e.g.*, the DNA in Table 5 of each of the Sugano et al references differs by only one nucleotide (at codon 30) from the DNA recited in claim 33 of the instant application) and also encodes a beta-interferon. Thus, the DNA of Sugano et al is embraced by claim 31 (parts 1) (a) and 1) (b) of the claim). The use of beta-interferon for treatment of human cancers is disclosed in each of the Sugano et al references at columns 1, lines 10-30) and the heterologous expression of DNA encoding beta-interferon is taught in each of the Sugano et al references at column 15 and claim 21-31 (U.S. Patent No. 5,514,567) and column 16 (U.S. Patent No. 5,326,859). Thus, the methods taught in each of the Sugano et al references are embraced by claims 31 and 34. The beta-interferon polypeptides (both the mature sequence and the sequence including the signal sequence) have the same sequences as those recited in claim 34 and are thus the same interferons as are embraced by both of the claims, no matter which DNA is used to produce the polypeptides. The U.S. Court of Appeals for the Federal Circuit concluded (*Fiers v. Sugano*, 25 USPQ2d 1601, U.S. Court of Appeals for the Federal Circuit, decided January 19, 1993),

that Sugano is entitled to rely on his disclosure as enabling since it sets forth a detailed teaching of a method for obtaining a DNA coding for β -IF and the Board did not err in determining that Fiers presented no convincing evidence impeaching the truth of the statements in Sugano's patent specification. We also conclude that Sugano's application satisfies the written description requirement since it sets forth the complete and correct nucleotide sequence of a DNA coding for β -IF The Board correctly determined that Sugano's March 19, 1980 Japanese application satisfies the requirements of section 112, first paragraph, and that Sugano thus met his burden to establish entitlement to that filing date.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (703) 308-0296. The fax phone number for Examiner Martinell's desktop workstation is (703) 746-5162. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 305-4028.

PLEASE NOTE THE NEW FAX NUMBER

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


James Martinell, Ph.D.
Primary Examiner
Art Unit 1631

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Attorney Docket No.: B8/B8 CIP DIV4

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant : Walter C. Fiers
Application No. : 08/452,658 Confirmation No. : 5499
Filed : May 25, 1995
For : DNA SEQUENCES, RECOMBINANT DNA
MOLECULES AND PROCESSES FOR PRODUCING
HUMAN FIBROBLAST INTERFERON-LIKE
POLYPEPTIDES
Group Art Unit : 1631
Examiner : James Martinell

New York, New York
June 24, 2005

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

Sir:

Applicant/Appellant ("Applicant") files this Appeal Brief in support of his appeal from the final rejection of claims 31, 33 and 34 in the May 28, 2004 Office Action, which action was made FINAL. Applicant filed a Notice of Appeal on November 24, 2004 and paid the required fee.

Applicant has filed concurrently herewith a Petition for a five-month extension of time for filing this Appeal Brief and has paid the required fee under 37 C.F.R. §§ 1.136(a) and

1.17(a)(5). With the extension, the time for filing this Appeal Brief is extended up to and including June 24, 2005. Thus, this Appeal Brief is timely filed.

The Director is hereby authorized to charge \$500.00 to Deposit Account No. 06-1075 (Order No. 000441.0031), in payment of the filing fee for the Appeal Brief, as required under 37 C.F.R. § 41.20(b)(2). The Director is also hereby authorized to charge any additional fees that may be due in connection with this Appeal Brief, or to credit any overpayment of the same, to Deposit Account No. 06-1075 (Order No. 000441.0031). A separate Transmittal Letter authorizing the Director to charge the Deposit Account is enclosed for these purposes (in duplicate).

In view of the arguments set forth below, the Board should find that the Examiner erred in rejecting claims 31, 33 and 34 under 35 U.S.C. § 102 (g) in view of the Sugano '567 or '859 patents and should reverse the Examiner and allow those claims.

I. Real Party In Interest

The real party in interest is Biogen Idec MA Inc., a corporation organized and existing under the laws of the Commonwealth of Massachusetts, and having an office and place of business at 14 Cambridge Center, Cambridge, Massachusetts 02142. The present assignee of this application is Biogen, Inc. Biogen merged with Idec and changed its name in November 2003. 37 C.F.R. § 41.37 (c)(1)(i).

II. Related Appeals And Interferences

There are three other appeals, known to applicant, his legal representative, or his assignee, that will directly affect or be directly affected by or have a bearing on the Board's

decision in the pending appeal. 37 C.F.R. § 41.37(c)(1)(ii). These appeals are being filed concurrently in the following co-pending applications:

- i. U.S. Patent Application 08/471,646, filed June 6, 1995.
- ii. U.S. Patent Application 08/253,843, filed June 3, 1994.
- iii. U.S. Patent Application 08/449,930, filed May 25, 1995.

III. Status Of Claims

Claims 31, 33 and 34, set forth in Appendix A, stand rejected in this application and are on appeal. Claims 1-30 and 32 were previously cancelled. 37 C.F.R. § 41.37(c)(1)(iii).

IV. Status Of Amendments

Applicant has not submitted any amendments subsequent to the Examiner's May 28, 2004 Final Office Action. 37 C.F.R. § 41.37(c)(1)(iv).

V. Summary Of Claimed Subject Matter

Claims 31, 33 and 34 recite a method of treating human cancers or tumors by administering to a patient a composition comprising a recombinant IFN- β polypeptide produced by a DNA sequence that is operatively linked to an expression control sequence. 37 C.F.R. §41.37(c)(1)(v).

The independent claim involved in the appeal is:

Claim 31 recites (and dependent claims 33 and 34) recites a method for treating human cancers or tumors by administering to a patient a therapeutically effective amount of a composition comprising a pharmaceutically acceptable carrier and a recombinant polypeptide

produced by a non-human host transformed by a recombinant DNA molecule comprising a DNA sequence selected from the group of DNA sequences (a) that hybridize to the DNA inserts of four specifically-named recombinant DNA molecules, three of those molecules being contained in transfected host cells that were deposited in a recognized culture collection, or (b) that are degenerates of those DNA sequences. The claimed DNA sequences are operatively linked to an expression control sequence in the recombinant DNA molecule. Support for these claims can be found at, e.g., page 1, lines 10-19; page 12, lines 30-35; page 13, lines 8-30; page 94, lines 13-20; and claims 1, 5, 18, 28 and 30, as originally filed.

VI. Ground Of Rejection To Be Reviewed On Appeal

The ground of rejection to be reviewed on this appeal is the rejection of claims 31, 33 and 34 under 35 U.S.C. § 102(g) as being anticipated by Sugano et al., U.S. Patent 5,514,567 (“the Sugano ‘567 patent”) or Sugano et al., U.S. Patent 5,326,859 (“the Sugano ‘859 patent”). 37 C.F.R. §41.37 (c)(1)(vi).

VII. Argument

The Rejection Of Claims 31, 33 and 34 Is Contrary To Law And Fact

The Examiner has finally rejected claims 31, 33 and 34 under 35 U.S.C. § 102(g) as being anticipated by the Sugano ‘567 patent or the Sugano ‘859 patent. Neither of the Sugano patents is 35 U.S.C. § 102(g) art to those claims.

A. The Sugano Patents Are Not 102(g) Art As A Matter Of Law

The Sugano patents are issued United States patents. As such, they are not 102(g) art as a matter of law and PTO practice.

35 U.S.C. §102(g) recites in pertinent part:

“A person shall be entitled to a patent unless –

(g)(2) before such person’s invention thereof, *the invention was made in this country by another inventor* who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other” (emphasis added).

An issued United States patent cannot form the basis of a 102(g) rejection. It is not evidence of actual reduction to practice in this country. *See* MPEP § 2138:

“To qualify as prior art under 35 U.S.C. 102(g), . . . *there must be evidence that the subject matter was actually reduced to practice*, in that conception alone is not sufficient. *See Kimberly-Clark*, 745 F.2d at 1445, 223 USPQ at 607. While filing of an application for patent is a constructive reduction to practice, the filing of an application does not itself provide evidence necessary to show an actual reduction to practice of any of the subject matter disclosed in the application as is necessary to provide the basis for an *ex parte* rejection under 35 U.S.C. 102(g)” (emphasis added).

See also, In re Clemens, 622 F.2d 1029, 1038-39; 206 USPQ 289, 298-99 (CCPA 1980) (even a United States patent based on an earlier-filed patent application is not 102(g) art).

B. The Sugano Patents Are Not 102(g) Art To Applicant’s Claims As A Matter of Fact

The earliest United States application that led to the Sugano patents was filed on October 27, 1980. Applicant’s claims are entitled to at least the June 6, 1980 filing date of his UK patent application 80.18701.

The Examiner has never denied that applicant is entitled to such benefit. Indeed, in a January 14, 2003 Office Action, the Examiner rejected, under 35 U.S.C. §102(e),

substantially the same claims that now stand rejected over the very same Sugano patents.

Applicant responded that the Sugano patents were not 102(e) art to his claims because he was entitled at least to the June 6, 1980 filing date of his UK application, which date preceded the October 27, 1980 earliest US filing date of the Sugano patents, i.e., the 102(e) date. *See* Reply to Office Action, July 14, 2003, pp. 3-4. In the face of this priority claim and argument, the Examiner withdrew the 102(e) rejections. *See* Office Action, November 7, 2003.

Accordingly, even if the Sugano patents were 102(g) prior art as a matter of law and PTO practice – which they are not – the rejection would still be in error because applicant has an earlier priority date than any United States filing date to which the Sugano patents may be entitled. For an *ex parte* 102(g) rejection, there must be a reduction to practice in the United States before applicant's invention. *See* 102(g), *supra*, p. 5.

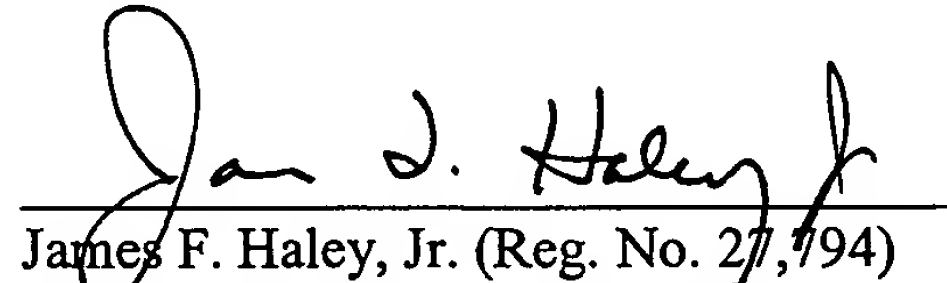
VIII. Claims Appendix

Appendix A sets forth claims 31, 33 and 34, which are pending in this application and are on appeal. 37 C.F.R. §37.41(1)(c)(viii).

IX. Conclusion

For all of the reasons set forth herein, applicant respectfully submits that the rejection of claims 31, 33 and 34 is erroneous and requests that the Board overturn it. All of the pending claims should be allowed.

Respectfully submitted,


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CLAIMS APPENDIX A
CLAIMS 31, 33 and 34, ON APPEAL

31. A method for treating human cancers or tumors comprising the step of administering to a patient in need of such treatment a therapeutically effective amount of a composition comprising:

- 1) a recombinant polypeptide produced by a non-human host transformed by a recombinant DNA molecule comprising a DNA sequence selected from the group consisting of:
 - (a) DNA sequences which hybridize to any of the DNA inserts of G-pBR322(Pst)/HFIF1, G-pBR322(Pst)/HFIF3 (DSM 1791), G-pBR322(Pst)/HFIF6 (DSM 1792), and G-pBR322(Pst)/HFIF7 (DSM 1793), and which code for a polypeptide displaying antiviral activity, and
 - (b) DNA sequences which are degenerate as a result of the genetic code to the DNA sequences defined in (a);

said DNA sequence being operatively linked to an expression control sequence in the recombinant DNA molecule; and

- 2) a pharmaceutically acceptable carrier.

33. The method according to claim 31, wherein said DNA sequence is selected from DNA sequences of the formulae:

ATGACCAACAAGTGTCTCCTCCAAATTGCTCTCCTGTTGTGCTTCTCCACTACAGCT
CTTTCCATGAGCTACAACCTTGCTTGGATTCCTACAAAGAAGCAGCAATTTTCAGTGT
CAGAAGCTCCTGTGGCAATTGAATGGGAGGCTTGAATACTGCCTCAAGGACAGGAT
GAACTTTGACATCCCTGAGGAGATTAAGCAGCTGCAGCAGTTCCAGAAGGAGGACG
CCGCATTGACCATCTATGAGATGCTCCAGAACATCTTTGCTATTTTCAGACAAGATT
CATCTAGCACTGGCTGGAATGAGACTATTGTTGAGAACCTCCTGGCTAATGTCTATC
ATCAGATAAACCATCTGAAGACAGTCCTGGAAGAAAAACTGGAGAAAGAAGATTTC
ACCAGGGGAAAACCTCATGAGCAGTCTGCACCTGAAAAGATATTATGGGAGGATTCT
GCATTACCTGAAGGCCAAGGAGTACAGTCACTGTGCCTGGACCATAGTCAGAGTGG
AAATCCTAAGGAACTTTTACTTCATTAACAGACTTACAGGTTACCTCCGAAAC, and
ATGAGCTACAACCTTGCTTGGATTCCTACAAAGAAGCAGCAATTTTCAGTGTGAGAAG
CTCCTGTGGCAATTGAATGGGAGGCTTGAATACTGCCTCAAGGACAGGATGAACTTT

GACATCCCTGAGGAGATTAAGCAGCTGCAGCAGTTCCAGAAGGAGGACGCCGCATT
GACCATCTATGAGATGCTCCAGAACATCTTTGCTATTTTCAGACAAGATTCATCTAG
CACTGGCTGGAATGAGACTATTGTTGAGAACCTCCTGGCTAATGTCTATCATCAGAT
AAACCATCTGAAGACAGTCCTGGAAGAAAACTGGAGAAAGAAGATTTACCCAGGG
GAAAACCTCATGAGCAGTCTGCACCTGAAAAGATATTATGGGAGGATTCTGCATTACC
TGAAGGCCAAGGAGTACAGTCACTGTGCCTGGACCATAGTCAGAGTGGAAATCCTA
AGGAACTTTTACTTCATTAACAGACTTACAGGTTACCTCCGAAAC.

34. The method according to claim 31 wherein the polypeptide is selected from polypeptides of the formulae:

Met-Thr-Asn-Lys-Cys-Leu-Leu-Gln-Ile-Ala-Leu-Leu-Leu-Cys-Phe-Ser-Thr-Thr-Ala-Leu-Ser-
Met-Ser-Tyr-Asn-Leu-Leu-Gly-Phe-Leu-Gln-Arg-Ser-Ser-Asn-Phe-Gln-Cys-Gln-Lys-Leu-Leu-
Trp-Gln-Leu-Asn-Gly-Arg-Leu-Glu-Tyr-Cys-Leu-Lys-Asp-Arg-Met-Asn-Phe-Asp-Ile-Pro-Glu-
Glu-Ile-Lys-Gln-Leu-Gln-Gln-Phe-Gln-Lys-Glu-Asp-Ala-Ala-Leu-Thr-Ile-Tyr-Glu-Met-Leu-
Gln-Asn-Ile-Phe-Ala-Ile-Phe-Arg-Gln-Asp-Ser-Ser-Ser-Thr-Gly-Trp-Asn-Glu-Thr-Ile-Val-Glu-
Asn-Leu-Leu-Ala-Asn-Val-Tyr-His-Gln-Ile-Asn-His-Leu-Lys-Thr-Val-Leu-Glu-Glu-Lys-Leu-
Glu-Lys-Glu-Asp-Phe-Thr-Arg-Gly-Lys-Leu-Met-Ser-Ser-Leu-His-Leu-Lys-Arg-Tyr-Tyr-Gly-
Arg-Ile-Leu-His-Tyr-Leu-Lys-Ala-Lys-Glu-Tyr-Ser-His-Cys-Ala-Trp-Thr-Ile-Val-Arg-Val-Glu-
Ile-Leu-Arg-Asn-Phe-Tyr-Phe-Ile-Asn-Arg-Leu-Thr-Gly-Tyr-Leu-Arg-Asn, and Met-Ser-Tyr-
Asn-Leu-Leu-Gly-Phe-Leu-Gln-Arg-Ser-Ser-Asn-Phe-Gln-Cys-Gln-Lys-Leu-Leu-Trp-Gln-Leu-
Asn-Gly-Arg-Leu-Glu-Tyr-Cys-Leu-Lys-Asp-Arg-Met-Asn-Phe-Asp-Ile-Pro-Glu-Glu-Ile-Lys-
Gln-Leu-Gln-Gln-Phe-Gln-Lys-Glu-Asp-Ala-Ala-Leu-Thr-Ile-Tyr-Glu-Met-Leu-Gln-Asn-Ile-
Phe-Ala-Ile-Phe-Arg-Gln-Asp-Ser-Ser-Ser-Thr-Gly-Trp-Asn-Glu-Thr-Ile-Val-Glu-Asn-Leu-
Leu-Ala-Asn-Val-Tyr-His-Gln-Ile-Asn-His-Leu-Lys-Thr-Val-Leu-Glu-Glu-Lys-Leu-Glu-Lys-
Glu-Asp-Phe-Thr-Arg-Gly-Lys-Leu-Met-Ser-Ser-Leu-His-Leu-Lys-Arg-Tyr-Tyr-Gly-Arg-Ile-
Leu-His-Tyr-Leu-Lys-Ala-Lys-Glu-Tyr-Ser-His-Cys-Ala-Trp-Thr-Ile-Val-Arg-Val-Glu-Ile-Leu-
Arg-Asn-Phe-Tyr-Phe-Ile-Asn-Arg-Leu-Thr-Gly-Tyr-Leu-Arg-Asn.